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File: USPT

Jul 22, 2003

DOCUMENT-IDENTIFIER: US 6596762 B2

TITLE: Antioxidant compositions and use for treatment of hepatic steatosis and steatohepatitis

Brief Summary Text (2):

The present invention provides formulations and methods for preventing and treating liver injury that occurs in hepatic steatosis and steatohepatitis, as well as diseases associated with these conditions, including, but not limited to, nonalcoholic steatohepatitis. The method includes the administration of a composition that includes selected antioxidant compounds.

Brief Summary Text (21):

Another embodiment of the present invention relates to a method of treating liver injury resulting from hepatic steatosis or steatohepatitis in a patient. The method includes administering to a patient that has or is at risk of developing hepatic steatosis or steatohepatitis a pharmaceutical composition consisting essentially of soluble Vitamin E, mixed carotenoids and selenium. In one embodiment, the method is used to treat a patient that has or is at risk of developing nonalcoholic steatohepatitis (NASH). In one aspect, the composition consists essentially of: (a) soluble vitamin E in an amount of between about 10 international units per kilogram body weight of the patient per day (IU/kg/day) and about 100 IU/kg/day; (b) mixed carotenoids in an amount of between about 0.1 milligram per kilogram body weight of the patient per day (mg/kg/day) and about 1 mg/kg/day; and, (c) selenium in an amount of between about 0.5 microgram per kilogram body weight of the patient per day (.mu.g/kg/day) and about 3 .mu.g/kg/day. Various embodiments of the composition are also encompassed as described above.

Brief Summary Text (24):

The present invention generally relates to compositions and methods to inhibit the biological events associated with the development and progression of hepatic steatosis and steatohepatitis and/or the symptoms associated with these conditions. More particularly, it is an object of the present invention to provide safe, inexpensive, non-surgical methods for the prevention and treatment of liver injury that occurs in hepatic steatosis, including, but not limited to, nonalcoholic steatohepatitis (NASH).

Brief Summary Text (26):

In accordance with one aspect of the present invention, there is provided a method of preventing and treating liver damage caused by hepatic steatosis, steatohepatitis and related liver diseases, including, but not limited to, nonalcoholic steatohepatitis. The method is useful for the treatment of mammalian organisms, and particularly human beings (together, hereafter referred to as "patients"), and includes the step of administering to patients that have or are at risk of developing hepatic steatosis a pharmaceutical formulation (composition) comprising the following compounds: soluble Vitamin E, mixed carotenoids (e.g., beta carotene), and selenium, each of said compounds of the formulation being present in an amount effective to prevent or treat liver injury that occurs in hepatic steatosis. In one embodiment, the pharmaceutical formulation of the present invention consists essentially of soluble Vitamin E, mixed carotenoids, and selenium. In another embodiment, the pharmaceutical formulation of the present

invention consists essentially of soluble Vitamin E, mixed carotenoids, and selenium and at least one additional agent that is useful for treating hepatic steatosis, steatohepatitis and related liver diseases, including, but not limited to, ursodeoxycholic acid, tauro-ursodeoxycholic acid, and derivatives thereof.

Brief Summary Text (50) :

The aforementioned compositions of the present invention can be particularly useful in the prevention and treatment of liver injury of any etiology caused by hepatic steatosis, steatohepatitis and related liver diseases, including, but not limited to, nonalcoholic steatohepatitis (NASH). They represent a balance of ingredients which serve not only to reduce the number of free radicals formed in the liver, but also to inhibit the metabolic oxidation of arachidonic acid. The more preferred formulations in accordance with the present invention also enhance the performance of the composition by transporting certain antioxidant ingredients in the formulation and by offering the formulation in a form suitable for long-term use. These compositions, when provided in sufficient dosage over a period of 24 hours, can be useful in the prevention and treatment of liver injury and fibrosis caused by hepatic steatosis, steatohepatitis and related liver diseases.

CLAIMS:

16. The method of claim 15, wherein said hepatic steatosis is nonalcoholic steatohepatitis.

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